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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

18N2/1223

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ART UNIT	PAPER NUMBER
~~ZISKA, S~~ 1804 1804	18

DATE MAILED: 12/23/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 10/10/97 & 7/16/97

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-3, ~~5~~, 6, 9-35 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☑ Claim(s) 31 is/are allowed.
☑ Claim(s) 1-3, 6, 9-30, 32-35 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-421-632/40000

This application should be reviewed for errors.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 6, 9-35 and newly added claims 36-39 are active and examined in this office action.

This office action is in response to the amendments filed July 16, 1997 and October 10, 1997. It is noted for the record that applicants submitted substantial amendments to the claims in the amendment of July 16 which were never examined due to the submission of the second amendment on October 10. New grounds of rejection are appropriate on both amendments filed and new grounds of rejection not indicated by the second amendment (as indicated by underlined phrases) were necessitated by the amendment of July 16.

The rejection of claims 2, 3, 6, 9, 10, 12-18, 20-30 and 32 under 35 USC 112, second paragraph, is withdrawn in view of the amendments to the claims.

The rejection of claims 34 and 35 under 35 USC 102(b) as being anticipated by Bajocchi or Berkner is withdrawn in view of the amendments to the claims.

The following represent new grounds of rejection necessitated by amendments to the claims.

Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Regarding the phrase "wherein the E2 gene or part thereof is the sole adenoviral gene" is vague and unclear because the other listed sequences: the ITR, the encapsulation sequence are adenoviral genes. This amendment was made in the July 16 amendment. Further, the change from "gene" to region is vague and unclear because the distinction between "gene" and "region" is not clear. Applicants have not pointed out support in the specification for "region" and none can be found.

Claims 1-3, 9, 10, 12, 13-16, 17, 18, 19-30, 33, 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Regarding claim 37, the phrase "all or part of and/or all or part of" is vague and unclear due to the ambiguity of the parts actually in the vector. Regarding claim 39, the claim is vague and unclear since because the phrase "whereby production of said genes is according to a desired mode of regulation" is ambiguous since the beginning of the claim renders the E4 nonfunctional. Further, the phrase "production of said genes" is not commensurate with the E4 genes which have been rendered nonfunctional. Regarding claim 1, claim 1 appears to be a duplicate of claim 36 or not patentably distinct therefrom. All claims dependent therefrom are therefore also rejected.

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkner. Berkner discloses adenoviral vectors wherein regions are deleted and Berkner suggests on page 620, column 1, top paragraph, that the E4 region should be deleted. In view of the open claim language in claims 36-39, the defective recombinant adenovirus can contain other adenoviral gene sequences and the claims are rendered obvious by Berkner. It would have been obvious to one of ordinary skill to modify the vectors of Berkner by substituting or deleting the E4 genes in view of the stated teachings of Berkner to do just that. According, the modification of the vectors by modifying or deleting the E4 region was within the ordinary skill in the art at the time the claimed invention was made. Therefore, the invention as a whole is prima facie obvious.

The allowability of claims 1, 11, 19 and 33 is withdrawn in view of the amendments to the claims necessitating new grounds of rejection.

Claim 31 remains allowable for reasons of record.